UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 18, 2012

MEMORANDUM

SUBJECT: Efficacy Review for EPA Reg. No. 4822-LII, Flamingo;
DP Barcode: 401555

FROM: Marcus Rindal, Microbiologist
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510P)

THRU: Tajah Blackburn, Ph.D., Microbiologist
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7/26/12

TO: Marshall Swindell PM 33/ Martha Terry
Regulatory Management Branch I
Antimicrobials Division (7510P)

APPLICANT: S.C. Johnson & Son, Inc.
1525 Howe Street
Racine, Wisconsin 53403

Formulation from the Label[1]:

Active Ingredient(s)	% by wt.
Hydrogen Peroxide	0.77%
OTHER INGREDIENTS	99.23%
Total	100.00%

1 Formulation confirmed to be within certified limits as stated on the CSF.

I BACKGROUND

The product, Flamingo (EPA File Symbol 4822-LII), is seeking registration as a new end use product. The applicant requested to register the product for use as a general disinfectant, sanitizer, and virucide on hard, non-porous, surfaces in residential and commercial environments such as homes, airplanes, busses, cars, churches, synagogues, cruise ships, daycare centers, dormitories, hotels, mobile homes, offices, schools, professional offices, kitchens, and bathrooms.

This submission contained a letter dated March t, 2012 from the applicant's agent to EPA (MRID # 487689-00) and the proposed label. The submission is a secondary application ("child") to the primary submission ("parent"), 89094-L, Floor Liquid. Studies for the parent product were conducted at ATS Labs, located at t285 Corporate Center Drive, Suite 110 Eagan, MN. 5512 t.

II USE DIRECTIONS

The ready-to-use product is designed for disinfecting and sanitizing hard non-porous surfaces including countertops, oven doors, microwaves exterior, range tops, range hoods, vinyl siding, floors, walls, sinks, showers, handrails, high chairs, hubcaps, garbage cans, tubs, washing machines, mirrors, plastic (patio) furniture, refrigerator exterior, shower doors, telephones, tires, lamp, lap tops, grills, window blinds, ceiling fans, cell phones, cribs, cutting boards, drains, dishwasher, faucets, furniture, exercise equipment, China, China cabinet, cabinets, changing tables, light fixtures, mudrooms, toilet (handles) (seat) (rim) (tank), glass, computer screens, range hood, range tops, artificial plants, baseboards, molding, trim, automobile interior (dash, seats, windows, windshield), automobile shops, bathroom surfaces, bicycles, boats, bookcase, pianos, pictures, remote controls, shower heads, diaper pails, dish racks, door knobs, glazed bathroom tiles, glazed ceramic tile, glazed porcelain surfaces, glazed procelain, linoleum, metal, polystyrene, sealed fiberglass, sealed synthetic marble, stainless steel, vinyl, and chrome.

Directions on the proposed label provide the following information regarding use of the product to disinfectant/sanitize hard non-porous surfaces:

FLOOR: To disinfect: Apply enough product to thoroughly wet surface. Allow surface to remain wet for 10 minutes and then (wipe) (mop). For heavily soiled areas, a precleaning is required.

To sanitize: Thoroughly wet surface. Allow to remain wet for 30 seconds and then (wipe) (mop). For heavily soiled areas, a precleaning is required.

Other directions on the proposed label provide the following information:
To Control, Inhibit, or Prevent Mold and Mildew: Spray surface until thoroughly wet and allow to sit on surface for at least 10 minutes. Retreat as necessary.

III. AGENCY STANDARDS FOR PROPOSED CLAIMS:

Disinfectants for Use on Hard Surfaces:
The effectiveness of disinfectants for use on hard surfaces must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products Test (for spray products). The tests require that sixty carriers must be tested with each of 3 samples, representing 3 different batches, one of which is at least 60 days old, against *Salmonella enterica* ATCC 10708 (for effectiveness against Gram-negative bacteria), *Staphylococcus aureus* ATCC 6538 (for effectiveness against Gram-positive bacteria). To support products labeled as "disinfectants," killing on 59 out of 60 carriers is required to provide effectiveness at the 95% confidence level.

Virucides:
The effectiveness of virucides against specific viruses must be supported by efficacy data that simulates, to the extent possible in the laboratory, the conditions under which the product is intended to be used. Carrier methods that are modifications of either the AOAC Use-Dilution Method (for liquid disinfectants) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray disinfectants) must be used. To simulate in-use conditions, the specific virus to be treated must be inoculated onto hard surfaces, allowed to dry, and then treated with the product according to the directions for use on the product label. One surface for each of 2 different product lots of disinfectant must be tested against a recoverable virus titer of at least 10^4 from the test surface for a specified exposure period at room temperature. Then, the virus must be assayed by an appropriate virological technique, using a minimum of four determinations per each dilution assayed. Separate studies are required for each virus. The calculated viral titers must be reported with the test results. For the data to be considered acceptable, results must demonstrate complete inactivation of the virus at all dilutions. When cytotoxicity is evident, at least a 3-log reduction in titer must be demonstrated beyond the cytotoxic level.

Sanitizer Test (for inanimate, non-food contact surfaces):
The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface over those on an untreated control surface. The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. Tests should be performed with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038). The ASTM method states that the inoculum employed should provide a count of at least 7.5×10^5 colony forming units per carrier. Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes.

Disinfectants for Use as Fungicides (Against Pathogenic Fungi):
The effectiveness of liquid disinfectants against specific pathogenic fungi must be supported by efficacy data using an appropriate test. The AOAC Use-Dilution Method may be modified to conform with the appropriate elements in the AOAC Fungicidal Test. Ten carriers on each of 2 product samples representing 2 different product lots must be employed in the test. Killing of the specific pathogenic fungi on all carriers is required.

Hard Surface Mildew Fungistatic Test:
This method is intended to be used in supporting fungistatic claims for the control, treatment, or prevention of fungi and subsequent mildew growth on hard surfaces. Use of this test method in no way supports claims for use of a product as a fungicide. The test is to be conducted on 10 glazed ceramic tiles for each of two product lots against *Aspergillus niger* (ATCC 6275). Ten untreated glazed tiles are to be used as the control, on which greater than 50% of each tile is to be covered with fungal growth after 7 days for the test to be considered valid. Growth observations are to be made visually after 7 days of incubation. If no visible growth is evident at the end of the test period, examination at a 15X magnification must take place. A product dosage is considered acceptable when all ten treated replicates are free of fungal growth.

Supplemental Claims:
An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum.

IV COMMENTS ON THE SUBMITTED STUDIES (originally submitted in support of the parent product, 89094-L, Floor Liquid)

1. MRID 487700-03 "AOAC Use-Dilution Method," Test Organisms: *Salmonella enterica* (ATCC 10708), and *Staphylococcus aureus* (ATCC 6538), for Floor Liquid, Study Director Anne Stemper. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121. Study completion date – January 10, 2012. Study Identification Number A11875.

The study was conducted against *Salmonella enterica* (ATCC 10708) and *Staphylococcus aureus* (ATCC 6538). Three lots of the product were tested (Lot FS-A-LCL >60 days old, Lot FS-UA-LCL-1, and Lot FS-UA-LCL-2) using the provided ATS Labs protocol LEH15070511.UD. The product was received as a ready to use liquid. The concentration of hydrogen peroxide in the product was verified 3-5 days prior to use in testing and 1 week following testing by a titration method. According to the provided Confidential Statement of Formula the active ingredient lower certified limit is 0.693% and testing was done at 0.72% for Lot FS-A-LCL, 0.67% for Lot FS-UA-LCL-1, and 0.74% for Lot FS-UA-LCL-2. Each test organism was prepared by inoculating 10 mL tubes of culture media from stock slants and performing daily consecutive transfers for a minimum of three but less than thirty transfers of 1 loopful (10 µL) of culture into 10 mL of culture media. The final culture was incubated 48 – 54 hours at 35 – 37°C. The upper portions of the culture were removed from the 48 - 54 hours cultures of the test system after vortex and settling of ≥10 minutes occurred. A soil load of 5% fetal bovine serum was added. The culture was transferred to the penicylinders at a ratio of one carrier per one mL of culture and the carriers were immersed for 15±2 minutes, transferred to sterile matted Petri plates and dried for 40 minutes at 35-37°C (40% RH). For each lot of test substance, contaminated and dried carriers were individually transferred by hook needle at staggered intervals to individual tubes containing 10.0 mL of test substance (RTU). The carriers were exposed for 10 minutes at 19.0°C-20.0° then transferred by wire hook at identical staggered intervals to 10 mL of Letheen Broth + 0.1% Sodium Thiosulfate + 0.01% Catalase. All subculture vessels and control plates were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were visually examined for the presence or absence of growth.

Representative subculture tubes showing growth were subcultured, stained and/or biochemically assayed to confirm or rule out the presence of the test organism. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier enumeration.

Note: Confidential Statement of Formula (CSF) contains a note to the reviewer addressing the tested active ingredient concentration.

2. MRID 487700-04 "AOAC Use-Dilution Method," Test Organism: *Escherichia coli* O157:H7 (ATCC 35150), for Floor Liquid, Study Director Joshua Luedtke. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121. Study completion date – January 26, 2012. Study Identification Number A12558.

The study was conducted against *Escherichia coli* O157:H7 (ATCC 35150). Two lots of the product were tested (Lot FS-A-LCL and Lot FS-UA-NC using the provided ATS Labs protocol JW01122111.UD.2. The product was received as a ready to use liquid. The test organism was prepared by inoculating a 10 mL tube of culture medium from a stock slant and performing daily consecutive transfers for a minimum of three but less than thirty transfers of 1 loopful (10 µL) of culture into 10 mL of culture media. The final culture was incubated 48 – 54 hours at 35 – 37°C. The upper portions of the culture were removed from the 48 - 54 hours cultures of the test system after vortex and settling of ≥10 minutes occurred. A soil load of 5% fetal bovine serum was added. The culture was transferred to the penicylinders at a ratio of one carrier per one mL of culture and the carriers were immersed for 15±2 minutes, transferred to sterile matted Petri plates and dried for 39 minutes at 35-37°C (40% RH). For each lot of test substance, contaminated and dried carriers were individually transferred by hook needle at staggered intervals to individual tubes containing 10.0 mL of test substance (RTU). The carriers were exposed for 10 minutes at 21.0° then transferred by wire hook at identical staggered intervals to 10 mL of Letheen Broth + 0.1% Sodium Thiosulfate + 0.01% Catalase. All subculture vessels and control plates were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were visually examined for the presence or absence of growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier enumeration.

Note: Confidential Statement of Formula (CSF) contains a note to the reviewer addressing the tested active ingredient concentration.

3. MRID 487700-05 "AOAC Use-Dilution Method," Test Organism: *Streptococcus pyogenes* (ATCC 19615), for Floor Liquid, Study Director Joshua Luedtke. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN 55121. Study completion date – February 14, 2012. Study Identification Number A12557.

The study was conducted against *Streptococcus pyogenes* (ATCC 19615). Two lots of the product were tested (Lot FS-A-LCL, and Lot FS-UA-NC) using the provided ATS Labs protocol JW01122111.UD.1. The product was received as a ready to use liquid. A culture of the test organism was prepared by using a stock plate to inoculate multiple agar plates and incubating for 2-4 days at 35-37°C in CO_2. Following incubation, an organism suspension was prepared in Fluid Thioglycollate Medium to target 1×10^8 CFU/mL. A final spectrophotometer absorbance reading of the suspension was determined to be at 0.878 using a

spectrophotometer calibrated to 620 nm. The final test culture was mixed thoroughly prior to use. A soil load of 5% fetal bovine serum was added. The culture was transferred to the penicylinders at a ratio of one carrier per one mL of culture and the carriers were immersed for 15±2 minutes, transferred to sterile matted Petri plates and dried for 38 minutes at 25-30°C (65% RH). For each lot of test substance, contaminated and dried carriers were individually transferred by hook needle at staggered intervals to individual tubes containing 10.0 mL of test substance (RTU). The carriers were exposed for 10 minutes at 20.0° then transferred by wire hook at identical staggered intervals to 10 mL of Brain Heart Infusion Broth + 0.01% Catalase. All subculture vessels and control plates were incubated for 48±2 hours at 35-37°C. Following incubation, the subcultures were visually examined for the presence or absence of growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier enumeration.

Note: Confidential Statement of Formula (CSF) contains a note to the reviewer addressing the tested active ingredient concentration.

Note- The protocol was amended to compensate for population control failure and the test was repeated with the change in the preparation of test organism using growth media Tryptic Soy Agar + 5% Sheep's Blood in place of Brain Heart Infusion Broth.

4. MRID 487700-06 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," Test Organism: Influenza A (H1N1) Virus (ATCC VR-1469), for Floor Liquid, Study Director Shanen Conway. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN 55121. Study completion date – February 6, 2012. Study Identification Number A12604.

The study was conducted against A/PR/8/34 strain of Influenza A (H1N1) virus (ATCC VR-1469). Rhesus monkey kidney (RMK) cells (obtained from ViroMed Laboratories, Inc., Cell Culture Division) were used as the host cell line. Three lots of the product were tested (Lot FS-UA-LCL, Lot FS-UA-LCL-2, and Lot FS-UA-NC) using the provided ATS Labs protocol JW01122111.FLUA.2. The product was received as a ready to use liquid. The stock virus was prepared by collecting supernatant fluid from disrupted 75 – 100% infected cultured cells in which the cell debris was separated and removed from the supernatant by centrifugation. The supernatant culture fluid was removed, aliquoted, and the high titer stock virus was stored at ≤ -70°C until the day of use. On the day of use, an aliquot of stock virus (ATS Labs Lot FLUA-29) was thawed and maintained at a refrigerated temperature until use in the assay. The virus culture was adjusted to contain a soil load of 5% fetal bovine serum. Virus films were prepared by inoculating 200 µL and spreading it uniformly over the bottoms of twenty (20) separate 100×15 mm sterile glass Petri dishes. The virus films were dried for 20 minutes at 20°C with 40% relative humidity. For each lot of test substance, five dried virus films were individually exposed to a 2.00 mL aliquot of the test substance and held covered for 10 minutes at room temperature (22.0°C). The virus films were completely covered with the test substance. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. The filtrates were titered by serial dilution and assayed for infectivity and/or cytotoxicity. RMK cells in multiwell culture dishes were inoculated with 100 µL of the test substance prepared dilutions in quadruplicate. The cultures were incubated at 36 – 38°C with 5 – 7% CO_2 and scored periodically for seven days for the presence or absence of

CPE, cytotoxicity, and for viability. Controls included those for viability, input virus control, dried virus control, cytotoxicity control, and neutralization confirmation. The calculation of titers was performed using the Spearman and Karber method.

Note: Confidential Statement of Formula (CSF) contains a note to the reviewer addressing the tested active ingredient concentration.

5. MRID 487700-07 "Virucidal Efficacy of a Disinfectant for Use on Inanimate Environmental Surfaces," Test Organism: Respiratory Syncytial virus (ATCC VR-26), for Floor Liquid, Study Director Mary J. Miller. Study conducted at ATS Labs 1285 Corporate Center Drive, Suite 110 Eagan, MN 55121. Study completion date – February 1, 2012. Study Identification Number A12592.

The study was conducted against Long strain of Respiratory Syncytial virus (ATCC VR-26). Human larynx carcinoma (Hep-2) cells (obtained from ViroMed Laboratories, Inc., Cell Culture Division) were used as the host cell line. Three lots of the product were tested (Lot FS-A-LCL, Lot FS-UA-LCL-2, and Lot FS-UA-NC) using the provided ATS Labs protocol JW01122111.RSV.3. The product was received as a ready to use liquid. The stock virus was prepared by collecting supernatant fluid from disrupted 75 – 100% infected cultured cells in which the cell debris was separated and removed from the supernatant by centrifugation. The supernatant culture fluid was removed, aliquoted, and the high titer stock virus was stored at ≤ -70°C until the day of use. On the day of use, an aliquot of stock virus (ATS Labs Lot NRSV-24) was thawed and maintained at a refrigerated temperature until use in the assay. The virus culture was adjusted to contain a soil load of 5% fetal bovine serum. Virus films were prepared by inoculating 200 µL and spreading it uniformly over the bottoms of twenty (20) separate 100 mm X 15 mm sterile glass Petri dishes. The virus films were dried for 20 minutes at 20°C with 50% relative humidity. For each lot of test substance, five dried virus films were individually exposed to a 2.00 mL aliquot of the test substance and held covered for 10 minutes at room temperature (20.0°C). The virus films were completely covered with the test substance. Just prior to the end of the exposure time, the plates were individually scraped with a cell scraper to resuspend the contents and at the end of the exposure time the virus-test substance mixtures were immediately passed through individual Sephadex columns utilizing the syringe plungers in order to detoxify the mixtures. The filtrates were titered by serial dilution and assayed for infectivity and/or cytotoxicity. Hep-2 cells in multiwell culture dishes were inoculated with 100 µL of the test substance prepared dilutions in quadruplicate. The cultures were incubated at 36 – 38°C with 5 – 7% CO_2 and scored periodically for seven days for the presence or absence of CPE, cytotoxicity, and for viability. Controls included those for viability, input virus control, dried virus control, cytotoxicity control, and neutralization confirmation. The calculation of titers was performed using the Spearman and Karber method.

V RESULTS

MRID #	ORGANISM	Number of Carriers with Growth/ Total Number of Carriers			Average Log_{10} CFU/Carrier
		Lot FS-A-LCL	Lot FS-UA-LCL-1	Lot FS-UA-LCL-2	
10 minutes contact period					
48770003	*Salmonella enterica*	0/60	0/60	0/60	6.88
48770003	*Staphylococcus aureus*	1/60	0/60	0/60	6.58

MRID #	ORGANISM	Number of Carriers with Growth/ Total Number of Carriers		Average Log_{10} CFU/Carrier
		Lot FS-A-LCL	Lot FS-UA-LCL-1	
10 minutes contact period				
48770004	*Escherichia coli* O157:H7	0/10	0/10	6.54
48770005	*Streptococcus pyogenes*	0/10	0/10	6.82

MRID #	ORGANISM	RESULTS $TCID_{50}$/100µL			Dried Virus Control Average $TCID_{50}$/100µL
		Lot FS-UA-LCL	Lot FS-UA-LCL-2	Lot FS-UA-NC	
10 minutes contact period					
48770006	Influenza A (H1N1)	$\leq 10^{0.50*}$	$\leq 10^{0.50*}$	$\leq 10^{0.50*}$	$10^{5.50}$

*Complete killing was observed at 10^{-1} to 10^{-7} dilutions

MRID #	ORGANISM	RESULTS $TCID_{50}$/100µL			Dried Virus Control Average $TCID_{50}$/100µL
		Lot FS-A-LCL	Lot FS-UA-LCL-2	Lot FS-UA-NC	
10 minutes contact period					
48770007	Respiratory Syncytial virus	$\leq 10^{0.50*}$	$\leq 10^{0.50*}$	$\leq 10^{0.50*}$	$10^{4.70}$

*Complete killing was observed at 10^{-1} to 10^{-5} dilutions

VI CONCLUSIONS

1. The submitted efficacy data support the use of the product, Floor Liquid, as a disinfectant with bactericidal activity against the following microorganisms on hard, non-porous surfaces in the presence of 5% organic soil load for 10 minute contact time:

Salmonella enterica	MRID # 487700-03
Staphylococcus aureus	MRID # 487700-03
Escherichia coli O157:H7	MRID # 487700-04
Streptococcus pyogenes	MRID # 487700-05

Complete killing was observed in the subcultures for the required number of carriers tested against the required number of product lots. Controls were acceptable: viability controls demonstrated growth, sterility controls did not show growth, neutralization effectiveness controls demonstrated acceptable neutralization.

2. The submitted efficacy data support the use of the product, Floor Liquid, as a disinfectant with virucidal activity against the following microorganisms on hard, non-porous surfaces in the presence of 5% organic soil load for 10 minute contact time:

Influenza A (H1N1)	MRID # 487700-06

Complete inactivation at all tested dilutions was shown for the required number of product lots tested. No cytotoxicity was observed. Controls were acceptable: viability control demonstrated growth, sterility control did not show growth, and neutralization effectiveness control demonstrated neutralization.

VII LABEL RECOMMENDATIONS

1. The product, Flamingo, label claims disinfectant efficacy with bactericidal activity against the following microorganisms in the presence of 5% organic soil load for a 10 minute contact period:

Salmonella enterica	ATCC 10708
Staphylococcus aureus	ATCC 6538
Escherichia coli O157:H7	ATCC 35150
Streptococcus pyogenes	ATCC 19615

These claims are **acceptable** as they are supported by the submitted data. New product efficacy testing must be performed at the lower certified limit. According to the provided Confidential Statement of Formula the active ingredient lower certified limit (LCL) is 0.693%. The three lots tested were found to be acceptable.

2. The product, Flamingo, label claims disinfectant efficacy with virucidal activity against the following microorganisms in the presence of 5% organic soil load for a 10 minute contact period:

Influenza **A** (H1N1)	ATCC VR- 1469
Respiratory Syncytial virus	ATCC VR- 26

These claims are acceptable as they are supported by the submitted data. New product efficacy testing must be performed at the lower certified limit. According to the provided Confidential Statement of Formula the active ingredient lower certified limit (LCL) is 0.693%. The three lots tested were found to be acceptable.

3. The product, Flamingo, label claims efficacy as a sanitizer with activity against the following microorganisms in the presence of 5% organic soil load for a 30 second contact period.
These claims are **unacceptable** as the data submitted do not include the appropriate testing required to support the sanitization claim.

4. The applicant must make the following changes to the proposed label:

- On pages 2, 8, and 14 (Table 5) of the proposed label, remove all claims and instructions related to fungicidal or mildewcidal claims (i.e., to control, inhibit, or prevent mold and mildew). No efficacy data were submitted or approved to support these claims. Remove the 10 minute Fungistatic claim against *Aspergillus niger.* No efficacy data to support this claim were submitted.
- On page 2 of the proposed label, correct the use directions "Squirt directly onto floor in in a 3' by 3' area using an **S** pattern" in the TO CLEAN section.

- Throughout the proposed label (pages 3-5, 7-8, 12-t3, 15, and 23-26), all references to quantitative efficacy claims of 99.9% must be associated with the appropriate organism and claims (i.e. quantitative log reduction claims for disinfection are not appropriate as the disinfection test is qualitative; while 3 $\log_{10}$ reduction (99.9%) claims are appropriate for non-food contact sanitization and virucidal claims in the presence of acceptable efficacy data.
- On pages 3, 5, and 9 of the proposed label, the registrant must qualify all claims stating "Kills cold virus". Efficacy data are required on least two of the qualifying viruses (Rhinovirus, Coronavirus, and Respiratory Syncytial virus (RSV) to support unqualified "cold claims". When data are generated on only one of the three viruses, the cold claim must be qualified.
- On pages 4-6 of the proposed label, the terms "oxygenated", and "will not harm surfaces" are unacceptable, as they imply safety and environmental preference.
- Throughout the proposed label, remove the claim "powerful" to describe all pesticidal claims. The qualifier implies heighten efficacy.
- On page 6 of the proposed label, the claims "Cleans almost/nearly/virtually everything in your home", "any hard surface", and "works all over your home" are unacceptable as they imply that the product can be used on surfaces and sites beyond what is proposed on the label.
- On page 6 of the proposed label, the claim "gently clean almost everything" is unacceptable. This claim implies that the product can be used on surfaces/sites beyond those listed and also implies safety and environmental preference.
- On pages 6 and 7 of the proposed label, the claim "Gentle/mild way to sanitize" and "Gentle for your surfaces" are unacceptable as they imply safety and environmental preference.
- On page 7 of the proposed label, remove the claims "Quick sanitary action" and "fast-acting sanitary". The Agency does not have a standard for sanitary, and this term is often confused with sanitization. Should the registrant chose to replace sanitization with sanitary, the claim is still unacceptable due to the use of the terms quick (which requires contact times ≤ 10 seconds) and fast (contact time not yet defined by the Agency)
- On pages 7, 8 and 28 of the proposed label, remove the terms "gentle" and "mild" as they imply safety and heighten efficacy.
- On page 7 of the proposed label, the claim "Gloves off cleaning and disinfecting" is unacceptable as it implies safety and environmental preference.
- On page 8 of the proposed label, the claim "Active brakes [sic] down dirt & dissolves into oxygen into oxygen and water" is inaccurate and must be removed from the label.
- The comprehensive list of potential use sites (Table 3, pages 9-12) include the following sites that conflict with the use directions/sites and supporting efficacy claims, and should be removed from the proposed label:
    - China
    - Cutting boards
    - Can openers
    - Dish racks
    - Food preparation areas
    - Stove tops
    - Grills

- On page 12 of the proposed label, the term "safe" is unacceptable as it is false or misleading.
- On pages 11-12 of the proposed label, the terms ceramic, cement, fiberglass, porcelain, porcelain enamel, stone, grout, granite, marble, and wood all reflect porous surfaces in the absence of qualifying information. These surfaces must be consistently qualified or removed from the proposed label
- Remove all references to use of product as a sanitizer including directions for use as a sanitizer, sites, and marketing claims (locations too numerous to list). No efficacy data to support this claim were submitted.
- The label provides disinfection use directions for floors only. No disinfection directions were provided for use on multiple sites other than floors. (See entire label)
- On the Table (Page 13), change the "0" to "O" for *E. coli* O157:H7.
- On page 15 of the proposed label, claims that the product "Kills % Germs with the power of/scent of/ fragrance name/scent" are false and misleading. Efficacy of the product is not mediate by the fragrances/scents in the product.
- On pages 23-25, and numerous other location of the proposed label, the terms "deep" and "tough" as descriptors for disinfection/sanitization are unacceptable as they imply heighten efficacy.
- On page 23 of the proposed label, remove the claim "The same ingredient used for disinfecting cuts and scrapes" as it expands the uses to skin.
- Remove all references and iterations of the claims "Pure", "biodegradable", "healthy home", "kinder", "friendly", "gloves off", "no gloves needed", and "Fume-Free" as they imply heighten safety and environmental preference.
- Remove all references and iterations of "active oxygen", "chlorine free", "bleach free", "oxidation/oxidizing", "no chlorine", "breaks down into/leaves behind only water and oxygen", "non-chlorine", "elements of water and oxygen(?)", and "accelerated/hi-speed hydrogen peroxide", for pesticidal claims.
- On page 28 of the proposed label, remove the following claim "Quick easy and convenient disinfecting". The Agency has determined that term "quick" pesticidal claims must demonstrate efficacy in ≤10 seconds.
- On page 28 of the proposed label, the registrant must define the statement "Hygiene beyond cleanliness".
- Allergen claims are limited to non-living allergens with the action of cleaning, removing, or reducing.
- Data Matrix does not indicate MRID numbers for submitted studies and *E.* coli should be changed to *E. coli* O157:H7".